

DECLARATION FOR UTILITY OR DESIGN
PATENT APPLICATION (37 CFR 1.63)

Attorney Docket No.: 2132.036
Inventor Name: Jackowski et al
COMPLETE IF KNOWN

☒ Decl. Sub. w/Initial Filing
☐ Decl. Sub. after Initial Filing (surcharge (37 CFR 1.15 (e)))

Application No:
Filing Date:
Group Art Unit:
Examiner Name:

As a below named inventor, I hereby declare that:

My residence, post office addr., and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BIPOLAR MARKER INDICATIVE OF DISEASE STATE HAVING A
MOLECULAR WEIGHT OF 1518 DALTONS

the specification which
☐ is attached hereto OR
☐ was filed on _____ As United States Application No. or PCT Intl. Appln. No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN NUMBERS:	COUNTRY:	FOREIGN FILING DATE:	PRIORITY NOT CLAIMED:	CERTIFIED COPY Yes	No

Additional foreign appln. nos. are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:

APPLICATION NUMBER(s): FILING DATE:

☐ Addnl. provisional appln. Nos. are listed on a Supplementary priority data Sheet PTO/SB/02B attached.

General Information	
Variable	Value
Study ID	12345
Study Title	Investigation of the Effects of a New Drug on Blood Pressure
Study Type	Randomized Controlled Trial
Study Location	University Hospital, Department of Medicine
Study Period	January 2020 to December 2021
Study Status	Completed
Study Design	Parallel, Double-Blind, Placebo-Controlled
Study Population	Adults aged 18-75 years with hypertension
Study Objectives	To evaluate the efficacy and safety of the new drug compared to placebo in reducing blood pressure.
Study Arms	<ul style="list-style-type: none"> Arm 1: New Drug (n=100) Arm 2: Placebo (n=100)
Study Outcomes	<ul style="list-style-type: none"> Primary Outcome: Change in systolic blood pressure (mmHg) at 12 weeks. Secondary Outcome: Change in diastolic blood pressure (mmHg) at 12 weeks. Tertiary Outcome: Adverse events and patient compliance.
Study Results	<ul style="list-style-type: none"> Primary Outcome: The new drug group showed a significantly greater reduction in systolic blood pressure compared to the placebo group (p < 0.001). Secondary Outcome: The new drug group also showed a significantly greater reduction in diastolic blood pressure compared to the placebo group (p < 0.001). Tertiary Outcome: The new drug group had a higher rate of adverse events (15%) compared to the placebo group (5%).
Study Conclusions	The new drug is effective in reducing blood pressure, but it is associated with a higher rate of adverse events compared to placebo.
Study Limitations	<ul style="list-style-type: none"> Short duration of the study (12 weeks). Single-center study. Small sample size.
Study Strengths	<ul style="list-style-type: none"> Randomized design. Double-blind design. Placebo-controlled design.
Study Funding	University of Medicine and Health Sciences
Study Ethics	Approved by the Institutional Review Board
Study Registration	Registered at ClinicalTrials.gov
Study Contact	Dr. John Doe, Principal Investigator
Study Date	2022-01-01

U.S. PARENT APPLICATION or PCT NUMBER:	PARENT FILING DATE:	PARENT PATENT NO: (if applicable)
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OR

Additional inventors are being named on the ____ Supplemental additional inventor(s)
Page 2 of 3) sheet(s) PTO/SB/02A attached hereto.

